H1N1 CRA All Options Refresher Training Webinar Transcript

September 9, 2009
1:00 pm CT

Coordinator: Welcome and thank you all for standing by. At this time, all parties are on a listen-only mode until the question and answer session of today's call. At that time, you may press star 1 if you would like to ask a question.

I would also like to inform parties that the call is being recorded. If you have any objections, you may disconnect at this time. And I'd now like to turn the conference over to Mr. Charles Williams. Thank you, sir, you may begin.

Charles Williams: [1]All right, thank you. Hello everyone and welcome to our H1N1 vaccine doses administered refresher training. And this is for all options for tracking vaccine doses administered for H1N1.

My name, as she mentioned, is Charles Williams and I am an SRA International contractor with CRA and the CRA Partner Outreach Liaison. And today I am joined by Ms. Jeanne Tropper, who is the CDC CRA team lead and also by our CRA trainer, Mr. Tony DaSilva and other members of our CRA development team and outreach team.

[2]Our agenda for today is as follows; we'll first learn the objectives for the training session, give background that we give on all of ours, just to make sure if there are new people on the call that they get a background of why we're doing the tracking.

Then we'll give training and overview of all three options as well as action items that each option and Project Areas need considered for the options. And

then we will end with upcoming events and then our normal question and answer period.

[3]So the refresher training session today focuses on a number of things, including understanding procedures for the Project Area setup, which will be demonstrated by Tony today, review and understanding guidelines for reporting aggregate data per each of the options, comprehending process and technical consideration.

And again, this is going to be for all of the options. And then we will focus on gaining awareness of steps for submitting and confirming aggregate account data. We will also cover identifying and managing potential quality control concerns for aggregate reporting during the tracking period.

[4]To give a little background, as many of you know, the National Strategy for Pandemic Influenza: Implementation Plan calls for monitoring of appropriate use of scarce pandemic influenza vaccines. And to accomplish this, states, as we also call Project Areas, will track vaccine doses administered and collect and aggregate the minimum data element and then transmit this information to CDC on a weekly basis.

CRA, or the Countermeasure and Response Administration, has been modified to provide three different ways for states or partners or Project Areas to report this information to us. [5]The first option, commonly knows as Option 1, or data exchange, is when the state enters data into their state immunization information centers system or any type of equivalent application or system. And then this information is extracted into a data file and sent to CDC via three different types of formats.

You have pipe-delimited file, XML file and your HL7 file. And then this file is uploaded to CRA through the CRA application or it is transferred to the CRA through PHINMS.

Then we have Option 2, which is your direct Web entry. And this is when the Project Area or state enters the data directly into CRA via the Web-based aggregate reporting screen or interface. And all the aggregate accounts are collected in a more manual process.

And then we have Option 3, which is your individual level of data entry. And this is when individual level data is entered directly into the CRA via the Web-based screening or interface. And then only the aggregate counts of the minimum data elements that we required here at CDC are sent to CDC.

[6]So the pandemic plan that I spoke of earlier has now been applied to the H1N1 response. CRA will be used to track doses administered initially and this will be a critical component for safety and insuring targeted groups are reached in the early stages. BRFSS will be running in parallel and will track usage with statistical methods as vaccine coverage increases.

[7]So to give you a few guidelines for reporting your aggregate data to CRA, first of all, each Project Area is sending data to CRA on a weekly basis. And this is reporting all aggregate accounts for the week by age group and by dose number. Reporting is required for each reporting period, even if no doses area administered for that week. So if no doses are administered that week, then you will simply report zeros for that week. But we do require that you send the reports for the reporting week.

And the reporting period is based on an MMWR week, which is defined as Sunday through Saturday. And then reporting is required by the end of the

day, Tuesday, which is 11:59 pm of your respective time zones. So we expect to receive information by 11:59 that Tuesday following the end of the reporting period.

[8]So before we get into our overview and training session, we'd like to give you a few definitions just to make sure you understand everything we're talking about and move forward with the training.

First of all, an event is the public health program or emergency responses that require the administration of countermeasures. H1N1 vaccine campaign has been defined as an event within CRA. And then we have user roles. CRA has role-based user access. The user can only access system functions that are appropriate to their specific role.

We actually have three roles now; we have the public health administrator role or PHA, then we have the data entry specialist role that is DES and then we have a new data entry specialist lite role, which is DESL and we will explain this more as we get into our presentation. And then also, the organization is the physical location where the vaccine or the countermeasures will be administered.

So now I will turn it over to Tony to begin his demonstration for the demonstration for CRA.

Tony DaSilva: [9]Thank you very much, Charles. Before we get into the details of reporting your accounts, it's important for us to step back for a moment and take a look at sort of some basic set up information that we might use as we prepare to collect our data.

We've already set up the event using the minimum data set, including vaccine types, aggregate groups and the Project Areas we support. But again, there's some basic setup tasks that you might be required to do. And these include adding users, adding organizations and adding any optional fields that are available that you might want to capture information in advance of all of the items contained in the minimum data set.

So what I'd like to do is bring up CRA and I'd like to log in. Let me make sure my log in name is correct.

Jeanne Tropper: And this is Jeanne. The optional fields are specifically geared toward the Option 3 user and Tony will go over that when we get to the Option 3 piece.

Tony DaSilva: Thank you, Jeanne. I'll log into the system. And I'm presented with the home page or the landing page of CRA. And first off, I want to bring your attention to the online help. All of the tasks that we will perform today are contained within the online help. And if you're familiar with online help, you should have no problem using this system.

It will give you the procedures for all the tasks we will cover today and then all of the other tasks that are supported by CRA. So please take a look at the system and refer to it in the event that you find that you have any questions using the system.

So let's begin. The first thing we'll do is add an organization. Adding organizations are available through the system set up menu. And you'll notice right off I'm logged in as the public health administrator and we must be logged in as the PHA in order to perform this task. We'll click on System Set Up and we'll click on Add Organization.

And the system presents me with the add organization page. And from here, it's a simple matter or entering the details of the organization so we'll just quickly walk through that - organization type, local government agency. Our address, and our zip.

Jeanne Tropper: Organization is a place where the actual vaccination will occur.

Tony DaSilva: Let me enter the phone number. And it's critical that we choose an organizational function and for our purposes here we will choose administration clinic. And any of the other organizational functions that might be appropriate to the organization that you're creating.

From here, we click Save. And the system prompts me that my record was created. We're not quite finished yet. All of the information that we entered displays here but we need to do one more thing. We need to assign this organization to an event. If we don't do that, we won't be able to capture information associated with this particular organization. We do that by expanding the events options and clicking on the Assign Organization Event link.

And we'll click that and we are presented with the Assign Organization Event page. And I have a number of events here but the one I'm particularly interested, of course, is the Novel Influenza H1N1 09 Event. So I'll choose that and click on Add and it will move over to the Selected Events side. And then from here, we click on Save and now that event is tied into this particular organization.

That's the process for entering organizations. Remember, when you do that, it's important you remember to assign the organization to an event or you won't be able to complete this task.

The next thing I want to show in terms of setup is working with users. We want to be able to add users to the application in order to support their data entry. Again, we do that through the system setup menu. So let me click on System Setup.

And we have Add Users. I'll click on Add User. And you'll see a number of items that I need to enter and the first thing I need to do is enter an email address. So I'll enter an email address. It has to be a valid email address, by the way. So I'll enter ewood@ar.gov. I'll click Next. And then we enter the details of our users.

You'll notice that red carrots are required fields and you can enter the required fields only or additional detail if that's appropriate for you. So we'll enter our first name, our last name and we'll stick to our required fields for the purposes of time here today. And enter a password and verify our password.

And then you'll need to choose a user role. We have three displayed here; Public Health Administrator, Data Entry Specialist and our new Data Entry Specialist Light role. We will talk about that in some detail as we continue for our presentation. So for our purposes here, I'll choose data entry specialist.

And once I choose that, you'll notice that the Assign Resources to User button becomes active. You'll need to click on that, just as we did with organizations. We need to assign an organization of this particular user. And we'll add her to the Hot Springs Clinic by clicking on the Add button. And then we will click Save and now our user has been created, login name of ewood@ar.gov.

That is the procedure for entering a user. If you have any questions regarding this, then I urge you to first take a look at the online help and then we are

available to you here through the CBC Help Desk for any questions you might have. I'll turn it back over to Charles.

Charles Williams: [10]Okay, thank you, Tony. We are now going to go into our detailed overview and training for our Option 1 users, those using the data exchange. So before we begin the actual training, we want to give some guidelines for reporting aggregate data via Option 1.

[11]First, the primary code 128 should be used to report aggregated age group and dose number to the CDC. This number is used for all vaccines based on any formulation of H1N1 vaccine. So again, when reporting through Option 1, please use primary code 128 and that will encompass all of the vaccines that has been administered for H1N1.

Then also, there's full replacement of aggregate reports. Full replacement of all recently aggregate reports or aggregate counts, this is a previous as well as a new aggregate count is required for each reporting period. Each week, the counts for the new week plus the counts for the previous week must be reported. And this may include changes from the previous week or anything that would have to be full replaced every week.

And then your aggregate accounts are placed and the accounts are to match with each replacement.

[12]This diagram here just shows how the full replacement of the aggregate reports should work. And just to go through this quickly, you have your Week 1 report, Week 1 doses administered, you have 100. So the next week or Week 2 of your report, again, 250 for your Week 2. And that's Week 2 exclusive of Week 1.

But then you notice that maybe you left five doses off of the previous week, so that's replaced with 105 to make up the five you missed previously. And then Week 3, you have 100 for Week 3 and then there were no changes for previous week and so on and so on. And so each week is full replacement and there may be changes on the previous week and then there may not be.

[13]So here are some process and technical considerations for Option 1 users. First, your local application should have the capability to collect the core data elements and/or the aggregate reports forum counts. The minimum data set should be extracted and put into one of three formats we mentioned earlier, the XML, the pipe delimited or HL7.

And this information is found in the data exchange specification document that is listed here and it can be found on our Web page. And then also, those who are using CRA to upload the information, you must have SDN digital specifically in order for it transfer the information to CRA.

And then also, you may need to consider and think of different policy control concerns, concerning the aggregate report form accounts from providers. And we will also get into some more detail with that in the - at the end of the presentation.

[14]So now for our scenario in training, I will turn it over to Tony. But this is when the data has been collected in the Project Areas, via an existing IIS, the Immunization Information System or any other application. And then the aggregate accounts are manually uploaded to the CRA for the reporting period.

Tony DaSilva: [15]Thank you, Charles. We'll go over some of the essential tasks we need to perform the CRA. Of course, we'll log into the system and then we'll upload a

data file to CRA. We'll note and correct any errors and warnings, and then we'll search the upload status.

And I want to make an important to note to PHINMS users. The upload process for PHINMS users is of course more automated and these steps don't necessarily apply. If you're interested in implementing PHINMS, it's important that you contact your CRA point of contact as soon as possible.

Let me bring up the application, I'll have to log out and log back in. I've logged into the system and I want to upload my file. So to do that, I'll click on Data Collection and I'll choose Upload Aggregate File. The system presents you with the Upload Aggregate File page and there is a browse button which you can click to locate your upload file. I have a file I created here for demonstration and I'll choose Open.

And then from here, it's just a simple matter of clicking the Upload button. The system will consume your file. And as it does, it'll send you a message indicating deployment, rather indicating that your file has been uploaded. And it will also send you an email, providing you the status of the upload when that, you know, when that upload is complete.

The system also displays a link, View Upload Details - and we can click on that to see the results of our upload. And we have our upload information here, the jurisdiction, the event, the upload IDs the system assigns to it, the date and time that you entered it and all this other information.

The think that we're most interested here for our purposes ids was our upload successful and in fact it was. But you'll also notice on the bottom of the page, there is a list of errors. Here I track warnings and errors. A warning is an

indication that there is an issue with your file but the warning will not prevent the file from being uploaded. And error is a fatal error.

If the system presents an error to you, it'll describe the error and display more or less the location of where that error is contained within your own target file. It'll be up to you to open up your file, make whatever changes you need to based on the information that the CRA provided to you and then upload your file again.

Fortunately for us, our warnings here simply indicate that these are elements of our data file that contains zero counts. So that is supportive as far as our Option 1 specification is concerned. So the file simply indicated that there's one in there but it accepted it successfully.

I will go back to the home page and then log out of the system. And that brings me to the end of the Option 1 training. Again, all of those procedures are contained within the online help and I urge you to renew that if you have any questions. I'll turn it back to Charles.

Charles Williams: [16]Thank you. Next, we will have our overview and then also training demonstration for Option 2, which is the Web-based aggregate. [17]One of the guidelines for Project Areas using Option 2 is the vaccine type **Novel-Influenza-H1N1-09, all formulations** should be used to report the aggregate age group and dose number to CDC.

So all vaccinations that have been administered in the reporting period should be classified in the all formulations label. [18]The process and technical considerations for Option 2 users include, first of all, you need to determine how the data will be entered into CRA. It can be one of two ways; one could

be that the aggregate data is submitted at the Project Area or state level only.
So the information will be submitted and confirmed at the Project Area level.

Or the data can be submitted at the provider or local level and then confirmed
at the Project Area or state level scenario. Based on how you determine the
information will be entered into CRA, you can also determine who will then
need access to CRA and then what role they will need to have.

Some technical considerations include staff entering the data online must have
access to the Internet, of course via the Web browser. And then staff
confirming data as the Projects Area level must have an SDN digital
certificate.

[19]So for the training, we have two scenarios for you. [20]I just mentioned them
earlier but to go a little more into detail, Scenario 1 is where the Project Area
enters accounts and confirms some accounts as well. So the data is collected at
the provider level and then this information is sent to the public health
authority and then is aggregated at the Project Area or the state level.

The public health administrator at the state level logs into CRA and submits
the confirmed aggregate data to the Project Area. [21]And then Scenario 2 is
where the provider enters the accounts and then the Project Area or the state
level confirms these accounts. Data is collected and then aggregate accounts
into the CRA at the provider level and then the PHA at the Project Area levels
confirms the accounts and submits to CRA.

Tony DaSilva: Thank you, Charles. We're going to go through the first scenario, Project Area
entered into confirmed accounts. And this scenario data is selected at the
provider level by a variety and manual and technical methods and then is
delivered to the public health authority. The public health authority aggregates

that data at the same project level and then submits those numbers into CRA based rather on the Project Area or state level.

Let me bring up the application and I will log in. All right, we're presented with the home page of the CRA application. And the first thing I'll do is click on Data Collection and click on Confirm Aggregate Reports. I'll need to enter my required aggregate report information and my jurisdiction displayed by default based on by my login. I'll need to choose the event I'm working with.

And once I do that, the vaccine information displays, the report date displays, the nearest calendar report date and for our purposes here I'll choose another.

So once we enter our period report date, click Next. And the Confirm Aggregate Report page displays. Since we're confirming these at the state and Project Area level, we'll assume that we'll have some sort of documentation that gives us all our accounts and we'll enter those accounts into the system here. You need to enter it for the All Formulations option and we'll click the link associated with that.

A popup window displays containing our dose number and our age groups. So for our purposes here, we'll 500 on the first doses and we'll enter information on our accounts – I'm not being particularly creative here. But as you notice, as I enter my information, the total continued to increment. It's critical that we match our total for our doses and our age groups information.

If we're satisfied that we have all our information, we'll click on the Confirm button and you'll see a green checkmark indicating that our accounts have been confirmed.

Let me logout and attack this from the second scenario, where providers enter accounts and then Project Area will confirm the total counts. In this scenario, the data selected and the aggregate accounts are entered into the CRA at the provider level. And then the public health administrator will log into the CRA and confirm the aggregate data from the Project Area there.

So let me login. I'll login as a data entry person. Based on our user role, we have access to certain functionalities and not to others. Here, as a data entry specialist, you'll see that have far fewer options available to me. All those options that are necessary for me to do my work.

And what I want to do here is first report on my aggregate accounts. So I will click on Data Collection and then choose Report Aggregate Accounts. My jurisdiction information is placed by default. This user has access to two different jurisdictions so we'll start with Alameda County. And unless we choose our organization, the event and product type information will display by default. It's a simple matter of clicking on the Next button and entering our account information.

We'll see where our page here is separated by aggregate accounts, age group and dose number. And the first thing we need to do is enter our report date. I will enter August 22. We can choose our vaccine type. And again, for aggregate reporting, we need to choose the All Formulations option.

Now once we choose that, the product information is displayed by default. And then again, it's a matter of entering our accounts. And that is total at the bottom. It needs to match the totals for your dose numbers.

Now I'm notorious for forgetting to enter my zeros. And if you happen to be like me, the system will want you to enter all the information. And once

you've collected all your information, click Save and Add Another. And you'll see your report information was saved.

Let's do this again since this is a relatively quick process. We'll just do it for another organization this user has access to. We entered one for Alameda County; let's enter one for Contra Costa Health Services.

I'll click on Next. The same as we did before with our dates, just use our product and enter our accounts. Make sure that our dose number and age group information matches. And once we're satisfied we have all our information, we'll click Save and add another. And the system prompts you and tells you your report has been saved.

Now that we've entered our information, we need to put on our public health administrator hat at the state level. So let me logout of here and simulate that by logging in as a PHA. Remember, the PHA has far more rights to the functionalities than the data entry specialist. So you'll see that reflected here on our menu options.

And what I want to do is tinker my report. So I'll choose Data Collection, Confirm Aggregate Report. And now this will roll up all the accounts that we entered for both of those organizations I showed you just a moment ago. I'm going to choose our event, our vaccine information will display by default. I want to make sure that I choose the correct report number.

If you find that when you enter your data and your accounts aren't there, that's always a good place to always troubleshoot first, if you have right reporting period. Once you select that, you click Next. And you saw this page just a moment ago as we were running through the first scenario. The same here, you'll see that are accounts are displayed.

I think I might be in the wrong place. Let me backup here. I'll click on Data Collection, Confirm Aggregate Report, choose my event, choose my reporting period and click on Next.

Well, I'm going to back out of that. The numbers are correct, yes.

Jeanne Tropper: It's already been confirmed.

Tony DaSilva: It's already been confirmed.

Jeanne Tropper: Confirmed it with the previous, you know, he went in confirmed.

Tony DaSilva: I logged out, logged out as a PHA, went through there. Well, I'm betting that this is an operator error so let me investigate that and come back to it. But for now, I want to talk to you about replacing counts, in the event that you're collecting information and you'll find that you'll have some counts available to you that come in after the fact.

You want to be able to enter that information and place those counts. This option here is a slide here for you immediately. But what I want to do before we do that is back up and show you how to search for this information in the event that you come into the system from another use case.

So search for information fortunately in CRA, it works precisely the same regardless of the element that we're looking for. So what I want to do is click to click Data Collection. I'll click on Search Aggregate Reports and I want to enter some basic information here. I've got my event, H1N1 09 and I've got a number of options here as well that that ought to do. Let's just find to share our reports.

Here is the report that we just entered. And you'll see the replace screen here. From here, it's just a simple matter to compare your accounts. And if you find that you have additional information that you want to enter, you can do that here. Let's say, for instance, we know that we received 200 more and our account has gone up to 550, it's important for us to remember to make sure that our dose number matches our age group number.

And from here, it's a simple matter of clicking on Replace Confirmed Report. The system will prompt you, are you sure you want to replace them? You click OK and then those reports will be updated. And if we hit Search again, you'll see that my new account displays there.

That brings me to the end of the Option 2 presentation. And I will turn it back over to Charles.

Charles Williams: [22]Thank you. We will now do our overview in training for Option 3. [23]And our guidelines for Option 3 users, all vaccine types can be used to track vaccine doses administered using Option 3. And then the individual vaccine and lot number information can also be collected using Option 3.

[24]Some process and technical consideration for Option 3 users include for process consideration determine who will collect and enter data, then who - determine what level of detail the vaccination data will be collected and then insure that the data entry staff or users or providers of organizations have been added and assigned to the event.

Technical considerations include staff entering data online must have access to the Internet via the Web browser, unless they are planning to use offline CRA. And also, staff access in CRA must also have a SDN digital certificate.

[25]So our scenarios for the training today, patient level vaccine doses administered data has been collected at the provider level and the entered into CRA. CRA aggregates patient level data entered by age group and dose number. Then the public health administrator logs in to CRA to confirm the aggregate data for the Project Area for that particular reporting period.

Tony DaSilva: [26]Thank you, Charles. We'll cover some essential tasks for Option 3. The first thing we'll do is enter patient demographic data. We'll look at the Add Countermeasure Page. We will look at all the patients that we added in our session, have a quick glance at the editing patient options.

And then we'll confirm the aggregate data through the Confirm Aggregate accounts page. Let me bring up CRA and I will need to log in. For this part of our presentation, we'll log in as the data entry specialist.

I'm presented with the home page of the application and I need to enter my patient information. I do that by clicking on Data Collection and Add Patient Countermeasures. I'm presented with the Add Patient Countermeasure page. We also call this our rapid data entry page because, of course, we can enter patient and countermeasure information in this one view.

You'll see that the patient identifier information is displayed by default. That's the system generated number. And of course, it's a tent box as well so you can change that information if you like. We'll enter our patient name; it'll ask you for a gender. And we want to enter a birthday. And as we do, you'll notice that the age group is calculated based on the birthday.

Our location defaults to a Little Rock clinic and we want to enter our administer date. And for our purposes here, I'll choose August 20th. We

changed our vaccine product. And in this instance, you have additional options and we'll choose for our purposes here the injectible form of the vaccination.

Our age group again has been calculated and so it's a matter of choosing our dose number and then clicking Add and Save Another Patient.

The patient record is created, the system prompts you that that occurred. It clears all your data entry out. Rather helpful here, where appropriate it will show you the last option that you selected, just to save you a little bit of data entry time. I'll enter another patient so we're clear on that process.

And our location defaults to Little Rock Clinic. We'll choose our administer date, our vaccine populates by default. And so all that's left for us to do is to choose our dose number and we'll click Save and Add Another Patient.

Again, the system clears. The data entry cascades to the next data entry options and you can continue to enter as many as you'd like.

Just a quick mention about the fields that you display here. These again are our minimum data set plus a few optional fields. Later on in the presentation, we will talk about configuring this information. But before we do that, I want to continue with the process of entering and confirming the accounts.

We entered two patients here. And it's always useful to go back and review some of our data entry. And we try to make that as easy as possible, particularly here by providing this link to view recently added patients. If we click with this link, we're presented with a View Recently Added Patients page.

And this shows you the last 20 patients that you've entered in your session. So that's a handy way of going back and either correcting information that you might have failed to put in or put in incorrectly or what have you. We can do that by clicking on the pencil icon, that's the Edit Patient button. We click on that.

The system will present us with the Edit Patient page and you'll notice right off that we have a far more field display for us than we had during our Rapid Data Entry page. That's simply because we set up the event, we indicated that those particular fields and in that instance, first name, last name, gender and date of birth were displayed.

And the others were kept on the Edit Page. So if you have additional items that you want to enter that aren't displayed on the Rapid Data Entry page, you can always edit the patient information and capture that information.

I won't go through this in any great detail but you'll see that everything's organized and has our countermeasure information is displayed here, we also have a field for follow up information that we can capture as well.

And if you have any questions on this, I urge you to look at the online help or certainly send me an email or go through the CRA Help Desk and we'll be happy to assist you.

What I want to do now is now that we've entered our patient level data and looked at editing patient information, I want to be able to confirm our report. To do that, I need to log out so you can imagine that the person at the clinic has entered all the information. Now it's come time for the public health administrator at the state or Project Area site to take all this information and submit their report

So just as we did before, we'll have to login. Now the system presents us with the home page and we need to confirm our report, so I'll click on Data Collection, Confirm Aggregate Report. My jurisdiction is selected by default, I choose my event information and be sure to choose my proper report. I entered the information on the 20 so that will roll into the report for the August 22 and I'll click on Next.

And you'll see the Confirm Aggregate Report page and accounts that we entered. And these are two measly accounts here under Injectible. And we need to confirm that information so we will click on Confirm. Our popup window displays and we're showing our accounts and our age groups and make sure that those two are appropriate and a match. And if we're satisfied that everything is okay, we'll click on Confirm.

And you'll see the green check box displayed for the Confirm option and we'll click on Done and close that out. We looked at replacing accounts just a moment ago but it's helpful for us to do that as well because that certainly is one of the options that will be available to you as an Option 3 user.

So let's do that now, we'll replace a confirmed report by clicking on Data Collection. And the first think we do again is search for that and we'll search the aggregate reports. And we'll have all our data fields right now but it's also a simple matter of clicking on the Search button. And that'll bring up all of the reports that you've submitted for this particular jurisdiction. You have our report date here and our link associated with it. And here are all our accounts.

And if we find that we have additional information that requires us to change that, we can do that here by simply entering our information, again, making

sure that our totals match and then clicking on the Replace Confirmed Report button. It'll prompt you and then tell you that your accounts are confirmed.

That brings me to the end of the training for Option 3 aggregate data collection. What I want to do is talk briefly about configuring the page once again.

We saw the data entry page, and I'll bring that up. As you recall, we have some very basic information here. Public health administrators have the right to add additional optional fields to the system. Optional fields are indicated by the lack of the carrot that's associated with them. The red carrot always means required field.

Say we wanted to add some additional information to a patient information or countermeasure information, we could do that by going through the event configuration options. And what we'll do is we'll add a field for patient information and also some fields for countermeasure information and then take a look at the results of our changes here on this page again.

To do that, we need to go behind the scenes on the event configuration side. So we'll click on event configuration and we need to search for our event. There's an option for entering the event name or the abbreviation. My event starts with the word "novel" so we'll just enter that and click on Search and my event name displays.

From here, we click on the event name link and we're presented with the Edit Event page. A fair amount of information here, we're got some basic event information, aggregate group information, the countermeasures that we were entering, group dispensing information, patient demographics and then all of

the jurisdictions that are associated with this particular event. In our case here, Arkansas.

What I'd like to do first is add a field to the countermeasures option. I'll click on Configure Countermeasures and you'll see the countermeasure information for our event that's organized by tabs: Vaccinations/Adjuvants/Diluents, Medications, Medical Material, and Isolation/Quarantine.

And each of these elements provide an additional set of standard fields that we can work with at the bottom of the page. You'll see here for vaccination, we have several options – Lot Number, Administered by, Follow up Data and Type, and Administration Body Route and Site. Those are displayed here.

If I want to add a field for follow up dates and types, I can click on that option and click on the Add button. And you'll see that that display is there. If I choose that, rather I want to make sure that you see this required field option here. If you want to make an option required for your purposes, you can click that and the red carrot will display for our data entry page and indicate to your users that this is a required field that must be entered.

We can click on the preview link - I'm having an issue here, as I see. The preview link will pop up a window that will show you a representation of the data entry fields that is presented to the user. It's a static representation, you really can't do anything with it other than preview what it would look like. Obviously I'm having some issues with this here and we'll investigate that and come back to that. But for now we'll click on Save.

And that's been added to our countermeasure options. And once we go back and look at it through the data entry option, you'll see that those fields have been added to the system. You'll notice that these follow up options here,

these are not available to you as a post-health administrator because the event was created here at CDC. So if you attempt to edit those there, you'll have a message displayed here, "You cannot edit the follow-up schedule. Your jurisdiction does not own this product."

Let's go an add an additional field to patient demographics. We'll have basic information here and we want to add maybe a telephone number. You scroll down, we'll see here a standard field and we'll just choose cell phone, for instance, and click on Add.

And once I click on Add, you'll see the up and down buttons are displayed here. So if I change the order in which that is displayed, I can click that there and the Preview button displays. For some reason it's operative here so we're fortunate that we can show that to you.

The Preview button again shows you a static representation of the page. It'll give you a sense of what it looks like to your users. I'll close that out and save my information. And if you scroll down, you'll see our cell phone option displays here. And the last thing we need to do is to make sure we click the Save button here, save all our information so that my event was updated.

Let's look at this from the perspective of a user. Click on Event Configuration, click on Data Collection rather, click on Add Patient Countermeasures and choose our event and click on Next. And with any luck, we'll see our additional fields on the page. You'll see my new field for cell phone and you'll see I have a follow up date option here and also I can communicate the type of follow up as well.

That brings me to the end of my presentation with regard to configuration. All of this again is contained within your online help system, I can't stress that enough. Please refer to that if you have any questions.

I'll log out and turn it over to Charles.

Charles Williams: [27]Thank you. Before we conclude our presentation with more information not requiring demonstration, I wanted to give an overview of the blended option that some Project Areas have decided to do. And this is the use of Option 2 and 3 combined in some way. We are not actually going to do a demonstration of this as we've just gone through a demonstration of both Options 2 and 3, where this blended option will require elements of both.

But blended option, Options 2 and 3, the scenario would be that the data collected at the provider level and some providers into the aggregate count directly into CRA directly. Some providers enter patient level data into CRA, which would actually be the Option 3. And then the public health administrator log into CRA to confirm the aggregate counts of both providers who used Option 2 of aggregate counts and Option 3 of the patient level data and confirm the counts at the state level.

[28]So now just give you a little information on accessing CRA, the application itself. First, some preparation activities include acquiring or renewing of your SDN digital certificate as necessary. And this is to be those that actually need the digital certificate, more information to come. And then also, use the CRA event named Novel Influenza H1N1 09 for associated setup tasks.

And of course, to log into CRA, you must first access the Secure Data Network, SDN, as the address listed on the screen. And then from there, you would access the CRA application on the SDN activity page.

So now I'm going to turn the presentation over to Mr. Jeanne Tropper.

Jeanne Tropper: [29]Thanks, Charles and thanks, Tony. I wanted to talk about the security waiver, which I know everybody's interested in. But first, before I do, there's just a couple of things with the demo I thought went very well. But the Scenario 2 where we were unable to show confirmation, the reason - we figured that out as we were doing this - is that the previous scenario, there were two scenarios, the previous one used the same date. So that's why that didn't show. But when we did the confirmation in Option 3, you saw how that worked.

The other thing is when we were doing - and this is relevant to the security waiver. When we were setting up the users and, Guy, correct me if I'm wrong, if you're an offline user, you would see the user name and password. Is that correct?

Guy Faler: Correct.

Jeanne Tropper: When you're online at CDC, when you set up a user, you would not be entering a user name and password. That will be assigned by CDC. So there will be a little different set up. So I didn't want to confuse you with the fact that when you do set up users using a security waiver, CDC will be assigning the user name and password.

That said, the security waiver. As you probably are painfully aware, accessing CDC systems using a digital certificate can be onerous when there are situations where you have a lot of non-traditional providers or people that don't traditionally access the system.

So recognizing that, we requested a security waiver to keep the security officer and we were granted it. And basically it geared towards the Option 2 and some extent Option 3 but really the Option 2 is where it's probably most useful.

Where you can set up what we're calling Data Entry Specialist Lite or DESL, to require user name and password only. This will not require them to have digital certificate. This means that this option will have very limited access to CRA. It will allow data entry only. It will not allow report generation or access.

The method by which we're going to support the user name and password will be available in a new guide, which is called guide for establishing CRA data entry specialist light for H1N1. When is that going to be available?

Guy Faler: It's ready today.

Jeanne Tropper: Okay, it's going to be posted after today. And so it will step you through what will be required. Essentially, you saw how Tony set up a user. So you will need to identify those people that you are going to have access the system, even this method. And the minimum data will be their name and a valid email.

And we suggest that you go ahead and begin to set these folks up. And then behind the scenes periodically the CRA application will create a file for our SDN folks. And they will then define the user name and password and those will be emailed out. Again, all this information will be in the guide.

Okay, so later we'll open up for Q&A. But this hopefully should make things easier for those of you have a significant non-traditional vaccinated population.

[30]So what are some of the considerations? First of all, of course, identify who will need the digital certificate and who will not. Digital certificate will still need to be required for the public health administrator who will be responsible for many of the setup tasks and who will be doing confirmations. So a Data Entry Specialist Lite that is just asking to use user name and password will not have the ability to confirm that.

The other thing will be that Option 1 users as well as the majority of Option 3 users would still need to have digital certificate. The exception on Option 3 would be those that have chosen the offline capability, since it's not within the CDC. Behind the firewall CDC, the security is really up to the Project Area.

So as we mentioned, the data entry staff must have a valid email address. And these people will need to be set up in the CRA application. And basically the important thing is begin to identify these folks, getting their emails and getting them set up within the CRA system and assigning them the appropriate roles.

And the next slide, I'm actually going to have Warren Williams talk to you about some of the kind of unique issues that we anticipate in the area of quality control.

Warren Williams: [31]Good afternoon everybody. This is something that's been coming up, we've gotten a couple of calls on it and we wanted to point this out. We've mentioned it in some previous calls. But for those users, mainly Option 2 users who are reporting aggregate counts and using their IIS to collect individual data, there will be a need at some point during the process to take into consideration the aggregate counts that come into your system in a timely fashion.

And then once the individual level counts come in through your IAS or other system, typically a few weeks later, you will have to go through some kind of process to reconcile the aggregate counts with the patient level data to avoid double counting the doses administered into the CRA system.

So this is just a concern to think about if you're using multiple modes of collecting information, both an aggregate count form process as well as an individual person level counting process. So this is something we've been trying to point out. There are a couple other techniques for managing this but we want to point this out, that this is something that has to be factored into the planning and next steps for the submission of the data.

[32]Our next slide, just a couple of reminders here. Our demonstration site is up and available for testing data entry and data submissions. You can also contact the Helpdesk for login and password information if you don't already have that.

The production side is accessed by the secure data network and is used to perform associated network tasks. I think we went over some of that training earlier today. So adding organizations and users, you can go ahead and do that through the production site now.

[33]We always like to close with a couple of action items for things that people need to be thinking about. Option 1 users, still submit your test files to Tony or your designated Project Area point of contact. I think we've got about 50% of the Option 1 users have already submitted their files. So we've got about 50% more to go. I know Tony would love to hear from you so please send your files into Tony according to the file specification format that you chose.

Go ahead and perform setup tasks as necessary for your Project Area. These are typically including organizations and/or users. Make sure that you have an active SDN digital certificate as required, develop quality control mechanisms for aggregate report forms when dealing with both aggregate report forms as well as the individual level of data entry reports that you may be getting.

Also expect for those who are interested in using the Date Entry Specialist Lite features of the CRA, we'll be sending out the guideline for how to do this and the process for getting your user name and password from those users that will be going out and available today.

[34]As usual, a group of contact here, you can contact anybody on this Web page as well as your point of contact and of course the CRA Helpdesk there. [35]We are going to keep a routine schedule of the Wednesday afternoon conference call and training sessions from here throughout the rest of the month and probably on into October as needed. We're just going to use these as any specific items that come up that need to communication on and certainly have an opportunity for further training and/or Q&A as necessary. So pencil these times in on your calendars.

And I think we're still trying to go at the 2:00 timeframe. So for planning purposes, you can tack your days on for the next series of Webinars and conference calls.

Charles Williams: Before we open for Q&A, I would just like to reiterate the fact that it is important for the PHAs to please add your users to the application as you identify who has access to applications. Please go into the application and add them as needed.

And if there are users that require digital certificate, then please send them to the PHIN Helpdesk for the actual application for the digital certificate. But in all cases, please add the users from your end and then it'll make the process go a little smoother on the CDC end.

[36]And now we will open up for questions.

Coordinator: If you would like to ask a question, please press star 1 on your touchtone phone, star 1 for questions. We'll give it a moment or two for our first question. I'll announce you by name when your line is open.

If you'd like to ask a question, press star 1 for questions. Maureen Cassidy, go ahead, your line is open.

Maureen Cassidy: What about the PHINMS users? Can we use the search aggregate count to look for our data in there, once it's been sent?

Charles Williams: Yes, you can.

Maureen Cassidy: Okay.

Charles Williams: Are there any other questions?

Coordinator: If you'd like to ask a question, press star 1 for questions.

Jeanne Tropper: That's great, everybody's all set.

Charles Williams: We have one online.

Jeanne Tropper: Let's see – "Clarification. If subsequent week reporting after the first week report cumulative, will report for Week 9, for instance, include cumulative reports from Week 1 through 8?"

Man: No, it will not.

Warren Williams: So you're an Option 2 user. You'll go ahead and just report your Week 9 data into the form as normal. If you had changes to Weeks 1 through 8, you would go back to that reporting week and make appropriate changes that way. So you would call it Week 1 and make any changes to that and then Week 2 and make changes to that.

Coordinator: And we have a question by phone by Rich Bradley. Go ahead, (Rich), your line is open.

Lisa Rasmussen: Lisa Rasmussen actually. My question was, as far as we're reporting Option 2 and we're doing this statewide, so we're not going to be doing different organizations, it's just a statewide reporting. Do we need to create the organization in there?

Ulrica Andujar: No - this is Ulrica. If you are logging in as the PHA and confirming, you just need to do the Confirm Aggregate Report step.

Lisa Rasmussen: Okay, we have to enter the information and then confirm what we just entered?

Ulrica Andujar: It's all on the same screen. So when you log in and go to data collection, you would click Confirm Aggregate Report and after entering it is confirming it. So when you enter it into the dose number and aggregate group tiers, when you click Confirm, then those counts are confirmed.

So you don't have to add organizations and then add the individuals counts per organization. If they're all being entered at the state level, just go to confirm, enter them, confirm and then you're done for the week.

Lisa Rasmussen: Okay, so when we open it up, we only go to that Confirm screen as opposed to the Report Aggregate Counts.

Charles Williams: Yes.

Ulrica Andujar: Right, right. Report Aggregate Count is only if the providers or at the provider level they're entering in counts specific to their clinic.

Lisa Rasmussen: Okay, that's where I got a little confused there. Thank you.

Ulrica Andujar: You're welcome.

Coordinator: Our next question from the phone comes from Christy Levy. Go ahead, Christy.

Regina Irvin: It's Regina Irvin. Hi everybody. You all had mentioned something about using a Code 128 when reporting our doses to you all. Can you elaborate on that a little bit more? We were trying to get the computer up and get connected.

Warren Williams: Are you an Option 1 user?

Regina Irwin: Yes.

Warren Williams: Okay, you'll just use CVX Code 128 to report all of your doses under that one generic formulation code.

Regina Irwin: Now what does CVX stand for?

Warren Williams: All right, it's a vaccine type code. You should - if you haven't looked at your data exchange specification guideline document, you want to take a careful look at that document and perhaps work with your IT staff and hopefully all of that stuff is in there and explained.

Ulrica Andujar: And there are sample messages in the document as well. So you can get a look at what it should look like for each format.

Tony DaSilva: This is Tony DaSilva, I'm happy to work with you individually if you have any questions, please feel free to send me an email or call me.

Regina Irwin: Is that Tony?

Tony DaSilva: aod7@cdc.gov.

Regina Irwin: Okay, we probably will give you a call.

Tony DaSilva: Looking forward to it.

Regina Irwin: Or email.

Charles Williams: Or you could call me, this is Charles and then we actually may just be able to set up a call to discuss all of this with you.

Regina Irwin: Okay, thank you, Charles and Tony. Thanks.

Coordinator: If you'd like to ask a question by phone, press star 1. Star 1 for questions by phone.

Charles Williams: No more questions?

Coordinator: We are showing no questions.

Charles Williams: Okay, well thank you everyone for joining us. And again, if you have questions that you just did not think of at this time, you can contact your CRA POC or email us at CRAhelp@cdc.gov. Thank you, have a good day.

Coordinator: This concludes today's conference call. Thank you for attending.

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